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Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of ISO 13485 cancels and replaces the second edition (ISO 13485:2003) and ISO/TR 14969:2004, which have been technically revised. It also incorporates the Technical Corrigendum ISO 13485:2003/Cor.1:2009. A summary of the changes incorporated into this edition compared with the previous edition is given in Annex A.

Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization:

— identifies its role(s) under applicable regulatory requirements;

— identifies the regulatory requirements that apply to its activities under these roles;

— incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by the:

a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;

b) organization's varying needs;

c) organization's particular objectives;

d) product the organization provides;

e) processes the organization employs;

f) organization's size and organizational structure;

g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

0.2 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

— When a requirement is qualified by the phrase “as appropriate”, it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:

 — product to meet requirements;

 — compliance with applicable regulatory requirements;

 — the organization to carry out corrective action;

 — the organization to manage risks.

— When the term “risk” is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.

— When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

— When the term “product” is used, it can also mean “service”. Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.

— When the term “regulatory requirements” is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term “regulatory requirements” is limited to requirements for the quality management system and the safety or performance of the medical device.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach.”

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements;

b) considering processes in terms of added value;

c) obtaining results of process performance and effectiveness;

d) improving processes based on objective measurement.

0.4 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B shows the correspondence between this International Standard and ISO 9001:2015.

This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management system meets all the requirements of ISO 9001.

0.5 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this International Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015[1], *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

1) Supersedes ISO 9000:2005.

3.1
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:

— use of a medical device,

— modification of a medical device,

— return of the medical device to the organization that supplied it, or

— destruction of a medical device

Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

3.2
authorized representative
natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

[SOURCE: GHTF/SG1/N055:2009, 5.2]

3.3
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: GHTF/SG5/N4:2010, Clause 4]

3.4
complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices

Note 1 to entry: This definition of "complaint" differs from the definition given in ISO 9000:2015.

3.5
distributor
natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

Note 1 to entry: More than one distributor may be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009, 5.3]

3.6
implantable medical device
medical device which can only be removed by medical or surgical intervention and which is intended to:

— be totally or partially introduced into the human body or a natural orifice, or

— replace an epithelial surface or the surface of the eye, and

— remain after the procedure for at least 30 days

Note 1 to entry: This definition of implantable medical device includes active implantable medical device

3.7
importer
natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

[SOURCE: GHTF/SG1/N055:2009, 5.4]

3.8
labelling
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: GHTF/SG1/N70:2011, Clause 4]

3.9
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7]

3.10
manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055:2009, 5.1]

3.11
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: GHTF/SG1/N071:2012, 5.1]

3.12
medical device family
group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function

3.13
performance evaluation
assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use

3.14
post-market surveillance
systematic process to collect and analyse experience gained from medical devices that have been placed on the market

3.15
product
result of a process

Note 1 to entry: There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

Note 3 to entry: This definition of "product" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 9000:2005[2], 3.4.2, modified]

3.16
purchased product
product provided by a party outside the organization's quality management system

Note 1 to entry: The provision of product does not necessarily infer a commercial or financial arrangement.

3.17
risk
combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: This definition of "risk" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 14971:2007, 2.16]

3.18
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[SOURCE: ISO 14971:2007, 2.22]

3.19
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO 11607-1:2006, 3.22]

2) Superseded by ISO 9000:2015.

3.20
sterile medical device
medical device intended to meet the requirements for sterility

Note 1 to entry: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

4 Quality management system

4.1 General requirements

4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;

b) apply a risk based approach to the control of the appropriate processes needed for the quality management system;

c) determine the sequence and interaction of these processes.

4.1.3 For each quality management system process, the organization shall:

a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes;

d) monitor, measure as appropriate, and analyse these processes;

e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system;

b) evaluated for their impact on the medical devices produced under this quality management system;

c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

4.1.5 When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

4.2 Documentation requirements

4.2.1 General

The quality management system documentation (see 4.2.4) shall include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures and records required by this International Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

The organization shall document a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;

b) the documented procedures for the quality management system, or reference to them;

c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;

b) specifications for product;

c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;

d) procedures for measuring and monitoring;

e) as appropriate, requirements for installation;

f) as appropriate, procedures for servicing.

4.2.4 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5.

A documented procedure shall define the controls needed to:

a) review and approve documents for adequacy prior to issue;

b) review, update as necessary and re-approve documents;

c) ensure that the current revision status of and changes to documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;

g) prevent deterioration or loss of documents;

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements.

4.2.5 Control of records

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;

b) establishing the quality policy;

c) ensuring that quality objectives are established;

d) conducting management reviews;

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.

5.3 Quality policy

Top management shall ensure that the quality policy:

a) is applicable to the purpose of the organization;

b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;

c) provides a framework for establishing and reviewing quality objectives;

d) is communicated and understood within the organization;

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives;

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are documented;

b) reporting to top management on the effectiveness of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.5).

5.6.2 Review input

The input to management review shall include, but is not limited to, information arising from:

a) feedback;

b) complaint handling;

c) reporting to regulatory authorities;

d) audits;

e) monitoring and measurement of processes;

f) monitoring and measurement of product;

g) corrective action;

h) preventive action;

i) follow-up actions from previous management reviews;

j) changes that could affect the quality management system;

k) recommendations for improvement;

l) applicable new or revised regulatory requirements.

5.6.3 Review output

The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to:

a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;

b) improvement of product related to customer requirements;

c) changes needed to respond to applicable new or revised regulatory requirements;

d) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed to:

a) implement the quality management system and to maintain its effectiveness;

b) meet applicable regulatory and customer requirements.

6.2 Human resources

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality;

b) provide training or take other actions to achieve or maintain the necessary competence;

c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

e) maintain appropriate records of education, training, skills and experience (see 4.2.5).

NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

6.3 Infrastructure

The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities;

b) process equipment (both hardware and software);

c) supporting services (such as transport, communication, or information systems).

The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance shall be maintained (see 4.2.5).

6.4 Work environment and contamination control

6.4.1 Work environment

The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

The organization shall:

a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;

b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

NOTE Further information can be found in ISO 14644 and ISO 14698.

6.4.2 Contamination control

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment;

c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).

The output of this planning shall be documented in a form suitable for the organization's method of operations.

NOTE Further information can be found in ISO 14971.

7.2 Customer-related processes

7.2.1 Determination of requirements related to product

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer but necessary for specified or intended use, as known;

c) applicable regulatory requirements related to the product;

d) any user training needed to ensure specified performance and safe use of the medical device;

e) any additional requirements determined by the organization.

7.2.2 Review of requirements related to product

The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements are defined and documented;

b) contract or order requirements differing from those previously expressed are resolved;

c) applicable regulatory requirements are met;

d) any user training identified in accordance with 7.2.1 is available or planned to be available;

e) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).

When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Communication

The organization shall plan and document arrangements for communicating with customers in relation to:

a) product information;

b) enquiries, contracts or order handling, including amendments;

c) customer feedback, including complaints;

d) advisory notices.

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

7.3 Design and development

7.3.1 General

The organization shall document procedures for design and development.

7.3.2 Design and development planning

The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.

During design and development planning, the organization shall document:

a) the design and development stages;

b) the review(s) needed at each design and development stage;

c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;

d) the responsibilities and authorities for design and development;

e) the methods to ensure traceability of design and development outputs to design and development inputs;

f) the resources needed, including necessary competence of personnel.

7.3.3 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use;

b) applicable regulatory requirements and standards;

c) applicable output(s) of risk management;

d) as appropriate, information derived from previous similar designs;

e) other requirements essential for design and development of the product and processes.

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE Further information can be found in IEC 62366-1.

7.3.4 Design and development outputs

Design and development outputs shall:

a) meet the input requirements for design and development;

b) provide appropriate information for purchasing, production and service provision;

c) contain or reference product acceptance criteria;

d) specify the characteristics of the product that are essential for its safe and proper use.

The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.

Records of the design and development outputs shall be maintained (see 4.2.5).

7.3.5 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:

a) evaluate the ability of the results of design and development to meet requirements;

b) identify and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).

7.3.6 Design and development verification

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5).

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5).

As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Validation shall be completed prior to release for use of the product to the customer.

Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5).

7.3.8 Design and development transfer

The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer shall be recorded (see 4.2.5).

7.3.9 Control of design and development changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.

Design and development changes shall be identified. Before implementation, the changes shall be:

a) reviewed;

b) verified;

c) validated, as appropriate;

d) approved.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).

7.3.10 Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing process

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

a) based on the supplier's ability to provide product that meets the organization's requirements;

b) based on the performance of the supplier;

c) based on the effect of the purchased product on the quality of the medical device;

d) proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

7.4.2 Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

a) product specifications;

b) requirements for product acceptance, procedures, processes and equipment;

c) requirements for qualification of supplier personnel;

d) quality management system requirements.

The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.5).

7.5 Production and service provision

7.5.1 Control of production and service provision

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

a) documentation of procedures and methods for the control of production (see 4.2.4);

b) qualification of infrastructure;

c) implementation of monitoring and measurement of process parameters and product characteristics;

d) availability and use of monitoring and measuring equipment;

e) implementation of defined operations for labelling and packaging;

f) implementation of product release, delivery and post-delivery activities.

The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

7.5.2 Cleanliness of product

The organization shall document requirements for cleanliness of product or contamination control of product if:

a) product is cleaned by the organization prior to sterilization or its use;

b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;

c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;

d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;

e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

7.5.3 Installation activities

The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation.

Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).

7.5.4 Servicing activities

If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.

The organization shall analyse records of servicing activities carried out by the organization or its supplier:

a) to determine if the information is to be handled as a complaint;

b) as appropriate, for input to the improvement process.

Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).

7.5.5 Particular requirements for sterile medical devices

The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices.

7.5.6 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results consistently.

The organization shall document procedures for validation of processes, including:

a) defined criteria for review and approval of the processes;

b) equipment qualification and qualification of personnel;

c) use of specific methods, procedures and acceptance criteria;

d) as appropriate, statistical techniques with rationale for sample sizes;

e) requirements for records (see 4.2.5);

f) revalidation, including criteria for revalidation;

g) approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems.

Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate.

Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

NOTE Further information can be found in ISO 11607-1 and ISO 11607-2.

7.5.8 Identification

The organization shall document procedures for product identification and identify product by suitable means throughout product realization.

The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.

The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

7.5.9 Traceability

7.5.9.1 General

The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).

7.5.9.2 Particular requirements for implantable medical devices

The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.

The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection.

Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).

7.5.10 Customer property

The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).

7.5.11 Preservation of product

The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.

The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

a) designing and constructing suitable packaging and shipping containers;

b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they shall be controlled and recorded (see 4.2.5).

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5);

b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);

c) have identification in order to determine its calibration status;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with documented procedures.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.5).

The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

NOTE Further information can be found in ISO 10012.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) demonstrate conformity of product;

b) ensure conformity of the quality management system;

c) maintain the effectiveness of the quality management system.

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.

The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require the organization to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

8.2.2 Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for:

a) receiving and recording information;

b) evaluating information to determine if the feedback constitutes a complaint;

c) investigating complaints;

d) determining the need to report the information to the appropriate regulatory authorities;

e) handling of complaint-related product;

f) determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.5).

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.5).

8.2.4 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;

b) is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE Further information can be found in ISO 19011.

8.2.5 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

8.2.6 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities.

Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.

For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.

8.3 Control of nonconforming product

8.3.1 General

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)

8.3.2 Actions in response to nonconforming product detected before delivery

The organization shall deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;

b) taking action to preclude its original intended use or application;

c) authorizing its use, release or acceptance under concession.

The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).

8.3.3 Actions in response to nonconforming product detected after delivery

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5).

The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).

8.3.4 Rework

The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.

After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework shall be maintained (see 4.2.5).

8.4 Analysis of data

The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

a) feedback;

b) conformity to product requirements;

c) characteristics and trends of processes and product, including opportunities for improvement;

d) suppliers;

e) audits;

f) service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5.

Records of the results of analyses shall be maintained (see 4.2.5).

8.5 Improvement

8.5.1 General

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

a) reviewing nonconformities (including complaints);

b) determining the causes of nonconformities;

c) evaluating the need for action to ensure that nonconformities do not recur;

d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;

e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;

f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken shall be maintained (see 4.2.5).

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

a) determining potential nonconformities and their causes;

b) evaluating the need for action to prevent occurrence of nonconformities;

c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;

d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;

e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

Annex A
(informative)

Comparison of content between ISO 13485:2003 and ISO 13485:2016

Table A.1 outlines the changes in this edition of this International Standard (ISO 13485:2016) compared with the previous edition (ISO 13485:2003).

Table A.1 — Comparison of content between ISO 13485:2003 and ISO 13485:2016

Clause in ISO 13485:2016	Comment on change compared with ISO 13485:2003
Foreword	— Clarifies the effect of the third edition of this International Standard.
Introduction 0.1 General	— Includes substantially more detail related to the nature of the organization covered by this International Standard's requirements and the life-cycle stages covered. — Explains that the requirements can be used by suppliers or other external parties either voluntarily or as a result of contract arrangements. — Alerts organizations about their obligations related to regulatory requirements focused on quality management systems. — Alerts organizations about differences in local regulation definitions and their obligation to understand how these definitions will affect their quality management system. — Adds the obligation to meet the organization's own quality management system requirements. — Specifically calls out the focus on the necessity to "meet customer and applicable regulatory requirements for safety and performance." — Emphasizes that the product requirements that are important are those related to safety and performance. — Adds two influences on the nature of the quality management system that were not in the original listing (organizational environment and regulatory requirements). — Clarifies that the organization does not have to align its documentation to the clause structure of this International Standard.
0.2 Clarification of concepts	— Adds two additional criteria associated with the description of appropriate requirements: — compliance with regulatory requirements; — the requirement is necessary for the organization to manage risks. — Limits application of risk to the safety or performance requirements of the medical device or meeting applicable regulatory requirements. — Clarifies that the term "documented" includes the need to establish, implement and maintain. — Clarifies that the term "product" applies to outputs that are intended for, or required by, a customer, or any intended output resulting from a product realization process.
0.3 Process approach	Explanation of process approach extended.
0.4 Relationship with ISO 9001	— States the relationship between ISO 13485:2016 and ISO 9001. — Indicates the structural relationship between ISO 13485:2016 and ISO 9001:2015 will be outlined in Annex B. — The use of italic text within standard to indicate changes from ISO 9001:2008 has been eliminated.

Table A.1 *(continued)*

Clause in ISO 13485:2016	Comment on change compared with ISO 13485:2003
1 Scope	— Indicates the applicability of this International Standard to organizations that are involved in one or more stages of the life-cycle of a medical device. — Indicates that this International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to medical device organizations. — Specifically calls out the responsibilities for monitoring, maintaining, and controlling outsourced processes. — Expands requirements that can be not applicable to those in Clauses 6 and 8. — Clarifies that the term "regulatory requirements" includes statutes, regulations, ordinances or directives and limits the scope of the "applicable regulatory requirements" to those requirements for the quality management system and the safety or performance of the medical device.
3 Terms and definitions	— Several new definitions added and some existing definitions refined.
4 Quality management system 4.1 General requirements	— Added requirement to document the role(s) of the organization. — Requires the determination of processes "taking into account the roles undertaken by the organization." — Requires the application of a "risk based approach to the control of the appropriate processes needed for the quality management system." — Adds requirements related to changes to processes. — Added requirements related to validation of the application of computer software used in the quality management system.
4.2 Documentation requirements	Includes control of records within the document control requirements. Lists the documents that would be included in the medical device file. New requirement related to protection of confidential health information. New requirement related to deterioration and loss of documents
5.6 Management review	— Includes requirement for the documentation of one or more procedures for management review and the requirement for management reviews at "documented planned intervals". — Lists of inputs and outputs of management review have been expanded.
6.2 Human resources	— New requirement for documentation processes of establishing competence, providing needed training and ensuring awareness of personnel.
6.3 Infrastructure	— Adds requirement that infrastructure prevents product mix-up and ensure orderly handling of product. — Adds information system to the listing of supporting services.
6.4 Work environment and contamination control	— Added documentation requirements for work environment. — Added requirement related to control of contamination with microorganism or particulate matter for sterile medical devices.
7.1 Planning of product realization	— Added requirements to list.
7.2 Customer-related processes	— Added requirements to list. — New requirement related to communication with regulatory authorities.
7.3.2 Design and development planning	— Added requirements to list. — Eliminated the requirement related to the management of the interfaces between different groups involved in design and development.
7.3.3 Design and development inputs	— Added requirements to list. — Added requirement that the requirements shall be able to be verified or validated.
7.3.5 Design and development review	— Added details of the contents of records.
7.3.6 Design and development verification	— Added requirement for documentation of verification plans and interface considerations. — Requirement added for records of verification.
7.3.7 Design and development validation	— Added requirement for documentation of validation plans, product to be used for validation and interface considerations. Requirement added for records of validation.
7.3.8 Design and development transfer	— New sub-clause added.
7.3.9 Control of design and development changes	— Adds the requirement that the evaluation of the change effect should be made on products in process and on the outputs of risk management and product realization processes — Added detail to consider in the determination of the significance of a design and development changes.

Table A.1 *(continued)*

Clause in ISO 13485:2016	Comment on change compared with ISO 13485:2003
7.3.10 Design and development files	— New sub-clause added.
7.4.1 Purchasing process	— Focuses the supplier selection criteria on the effect of the supplier performance on the quality of the medical device, the risk associated with the medical device, and the product meeting applicable regulatory requirements. — New requirements added related to monitoring and re-evaluation of suppliers, and action to be taken when purchasing requirements are not met. — Provides addition details related to the content of the records.
7.4.2 Purchasing information	— New requirement added to include notification of changes in purchased product.
7.4.3 Verification of purchased product	— New requirements added on the extent of verification activities and action to be taken when the organization becomes aware of any changes to the purchased product.
7.5.1 Control of production and service provision	— Adds details related to the controls for carrying out production and service provision.
7.5.2 Cleanliness of product	— Added a requirement to the list.
7.5.4 Servicing activities	— New requirement for analysis of records for servicing activities.
7.5.6 Validation of processes for production and service provision	— Added requirements to the list — Adds details related to situations requiring procedures. — Relates the specific approach to software validation to the risk associated with the use of the software. — Adds requirements related to the validation records.
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	— Added requirements for sterile barrier systems.
7.5.8 Identification	— Added requirement for unique device identification. — New requirement for a documented procedure for product identification and regarding identification and product status during production
7.5.11 Preservation of product	— Adds details as to how preservation can be accomplished.
8.2.1 Feedback	— Indicates that feedback should come from production and post-production activities. — Adds a requirement to utilize feedback in risk management processes in order to monitor and maintain product requirements.
8.2.2 Complaint handling	— New sub-clause.
8.2.3 Reporting to regulatory authorities	— New sub-clause.
8.2.6 Monitoring and measurement of product	— Adds requirement to identify the test equipment used to perform measurement activities.
8.3 Control of nonconforming product	— Added details related to kinds of controls that shall be documented. — Generalized the requirement to include any investigation and the rationale for decisions. — Adds requirements related to concessions. — Separated requirements for nonconformities detected before delivery, detected after delivery and rework. — Adds requirements for records related to the issuance of advisory notices.
8.4 Analysis of data	— Adds the requirement to include determination of appropriate methods, including statistical techniques and the extent of their use. — Adds detail to list of inputs.
8.5.2 Corrective action	— Adds the requirement to verify that the corrective action does not have an adverse effect. — Added requirement for corrective action to be taken without undue delay.
8.5.3 Preventive action	— Adds the requirement to verify that the preventive action does not have an adverse effect.

Annex B
(informative)

Correspondence between ISO 13485:2016 and ISO 9001:2015

Tables B.1 and B.2 show the correspondence between ISO 13485:2016 and ISO 9001:2015.

Table B.1 — Correspondence between ISO 13485:2016 and ISO 9001:2015

Clause in ISO 13485:2016	Clause in ISO 9001:2015
1 Scope 4.1.1 (no title)	1 Scope 4.3 Determining the scope of the quality management system
4 Quality management system	4 Context of the organization 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes 8.4 Control of externally provided processes, products and services
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 7.5.1 General
4.2.3 Medical device file	*No equivalent clause*
4.2.4 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented information
4.2.5 Control of records	7.5.2 Creating and updating 7.5.3 Control of documented information
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy 5.2.1 Establishing the quality policy 5.2.2 Communicating the quality policy
5.4 Planning	6 Planning
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review input	9.3.2 Management review inputs
5.6.3 Review output	9.3.3 Management review outputs

Table B.1 *(continued)*

Clause in ISO 13485:2016	Clause in ISO 9001:2015
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment and contamination control	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements for products and services
7.2.1 Determination of requirements related to product	8.2.2 Determining the requirements for products and services
7.2.2 Review of requirements related to product	8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services
7.2.3 Communication	8.2.1 Customer communication
7.3 Design and development	8.3 Design and development of products and services
7.3.1 General	8.3.1 General
7.3.2 Design and development planning	8.3.2 Design and development planning
7.3.3 Design and development inputs	8.3.3 Design and development inputs
7.3.4 Design and development outputs	8.3.5 Design and development outputs
7.3.5 Design and development review	8.3.4 Design and development controls
7.3.6 Design and development verification	8.3.4 Design and development controls
7.3.7 Design and development validation	8.3.4 Design and development controls
7.3.8 Design and development transfer	8.3.4 Design and development controls
7.3.9 Control of design and development changes	8.3.6 Design and development changes 8.5.6 Control of changes
7.3.10 Design and development files	7.5.3 Control of documented information
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing process	8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.4.2 Type and extent of control 8.4.3 Information for external providers 8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.2 Cleanliness of product	*No equivalent clause*
7.5.3 Installation activities	*No equivalent clause*
7.5.4 Servicing activities	*No equivalent clause*
7.5.5 Particular requirements for sterile medical devices	*No equivalent clause*
7.5.6 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier system	*No equivalent clause*
7.5.8 Identification	8.5.2 Identification and traceability
7.5.9 Traceability	8.5.2 Identification and traceability
7.5.10 Customer property	8.5.3 Property belonging to customers or external providers
7.5.11 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources

Table B.1 *(continued)*

Clause in ISO 13485:2016	Clause in ISO 9001:2015
8 Measurement, analysis and improvement	9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Feedback	8.5.5 Post-delivery activities 9.1.2 Customer satisfaction
8.2.2 Complaint handling	9.1.2 Customer satisfaction
8.2.3 Reporting to regulatory authorities	8.5.5 Post-delivery activities
8.2.4 Internal audit	9.2 Internal audit
8.2.5 Monitoring and measurement of processes	9.1.1 General
8.2.6 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs
8.3.1 General	10.2 Nonconformity and corrective action
8.3.2 Actions in response to nonconforming product detected before delivery	8.7 Control of nonconforming outputs
8.3.3 Actions in response to nonconforming product detected after delivery	8.7 Control of nonconforming outputs
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 General	10.1 General 10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	0.3.3 Risk-based thinking 6.1 Actions to address risks and opportunities 10.1 General 10.3 Continual improvement

Table B.2 — Correspondence between ISO 9001:2015 and ISO 13485:2016

Clause in ISO 9001:2015	Clause in ISO 13485:2016
1 Scope	1 Scope
4 Context of the organization	4 Quality management system
4.1 Understanding the organization and its context	4.1 General requirements
4.2 Understanding the needs and expectations of interested parties	4.1 General requirements
4.3 Determining the scope of the quality management system	4.1 General requirements 4.2.2 Quality manual
4.4 Quality management system and its processes	4.1 General requirements
5 Leadership	5 Management responsibility
5.1 Leadership and commitment	5.1 Management commitment
5.1.1 General	5.1 Management commitment
5.1.2 Customer focus	5.2 Customer focus
5.2 Policy	5.3 Quality policy
5.2.1 Establishing the quality policy	5.3 Quality policy
5.2.2 Communicating the quality policy	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities	5.4.2 Quality management system planning 5.5.1 Responsibility and authority 5.5.2 Management representative
6 Planning	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7 Support	6 Resource management
7.1 Resources	6 Resource management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.2 Human resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4.1 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.5.1 General	7.6 Control of monitoring and measuring equipment
7.1.5.2 Measurement traceability	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	6.2 Human resources
7.2 Competence	6.2 Human resources
7.3 Awareness	6.2 Human resources
7.4 Communication	5.5.3 Internal communication
7.5 Documented information	4.2 Documentation requirements
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.4 Control of documents 4.2.5 Control of records
7.5.3 Control of documented Information	4.2.3 Medical device file 4.2.4 Control of documents 4.2.5 Control of records 7.3.10 Design and development files
8 Operation	7 Product realization
8.1 Operational planning and control	7.1 Planning of product realization
8.2 Requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Communication
8.2.2 Determining the requirements for products and services	7.2.1 Determination of requirements related to product

Table B.2 *(continued)*

Clause in ISO 9001:2015	Clause in ISO 13485:2016
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	7.3.1 General
8.3.2 Design and development planning	7.3.2 Design and development planning
8.3.3 Design and development inputs	7.3.3 Design and development inputs
8.3.4 Design and development controls	7.3.5 Design and development review 7.3.6 Design and development verification 7.3.7 Design and development validation 7.3.8 Design and development transfer
8.3.5 Design and development outputs	7.3.4 Design and development outputs
8.3.6 Design and development changes	7.3.9 Control of design and development changes
8.4 Control of externally provided processes, products and services	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased product
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.6 Validation of processes for production and service provision
8.5.2 Identification and traceability	7.5.8 Identification 7.5.9 Traceability
8.5.3 Property belonging to customers or external providers	7.5.10 Customer property
8.5.4 Preservation	7.5.11 Preservation of product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision 7.5.3 Installation activities 7.5.4 Servicing activities 8.2.2 Complaint handling 8.2.3 Reporting to regulatory authorities 8.3.3 Actions in response to nonconforming product detected after delivery
8.5.6 Control of changes	7.3.9 Control of design and development changes
8.6 Release of products and services	7.4.3 Verification of purchased product 8.2.6 Monitoring and measurement of product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product
9 Performance evaluation	8 Measurement, analysis and improvement
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement
9.1.1 General	8.1 General 8.2.5 Monitoring and measurement of processes 8.2.6 Monitoring and measurement of product
9.1.2 Customer satisfaction	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaint handling
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.4 Internal audit

Table B.2 *(continued)*

Clause in ISO 9001:2015	Clause in ISO 13485:2016
9.3 Management review	5.6 Management review
9.3.1 General	5.6.1 General
9.3.2 Management review inputs	5.6.2 Review input
9.3.3 Management review outputs	5.6.3 Review output
10 Improvement	8.5 Improvement
10.1 General	8.5.1 General
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual improvement	5.6.1 General 8.5 Improvement

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